UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

MAR 7 1996

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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,634,697, which issued January 6, 1987, was filed on February 12, 1996, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application (CEDAX® in the form of ceftibutin capsules) has been subject to a regulatory review period within the meaning of 35 U.S. C. § 156(g) before its first commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S. C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. However, it is noted that applicant has also filed an application for patent term extension of U.S. Patent No. 4,634,697 based upon CEDAX® in the form of ceftibutin for oral suspension and two applications for patent term extension of U.S. Patent No. 4,812,561 based upon regulatory review of CEDAX® (one application based upon ceftibutin capsules and one based upon ceftibutin for oral suspension). Election will be required of a single patent and a single product.

Hiram A. Bernstein
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cc: Thomas D. Hoffman
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